Contains No CBI

RHÔNE-POULENC

RHÔNE-POULENC INC.
CN 7500, CRANBURY, NJ 08512-7500
TELEPHONE: (609) 395-8300

(A)

8EHQ-92-12075
INIT
88920010313

October 27, 1992

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 513 377 997

Document Processing Center (TS-790)
Attn: Section 8(e) Coordinator (CAP Agreement)
Office of Toxic Substances
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS - 0131

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed report provides information on the following chemical substance:

Product Name:	DV 1143 Glycol Glycidyl Ether
CAS Registry No:	2224-15-9
CAS Registry Name:	2,2'-[1,2-ethanediylbis(oxymethylene)]bisoxirane

2/7/95

(2)

The title of the enclosed report is:

Approximate Acute Oral Toxicity (LD_{50}) in Rats

The following is a summary of the adverse effects in this report.

Decreased activity, ataxia, salivation, urination, and tremors were observed in animals surviving to study termination as well as in those dying during the study. The oral LD_{50} of the test material was found to be 2.50 ml/kg.

RPI does not claim any portion of the information in this submission to be TSCA confidential business information (TSCA CBI).

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance.

RPI has submitted a Primary Skin Irritation study on this material under the CAP Agreement; see RP CAP Report No. RPS-0132.

In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919)549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,

Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
(609)860-3589

CEMjr/mm
Enclosures

(3)

CAP ID No. SCR-BAK-0741
Reviewed for Sec. 8 (e)
Compliance Program
On 10/1/81 By BAK

FDRL

FOOD AND DRUG Research LABORATORIES, INC.

WAVERLY RESEARCH CENTER
Route 17C
P. O. Box 107
Waverly, New York 14892
(607) 565-2931

R E P O R T

Submitted to: Alcolac, Inc.
3440 Fairfield Road
Baltimore, Maryland 21226

Date: March 28, 1978

Laboratory No. 5701

Sample: Clear viscous liquid.

Marking: DV-1143; Cyclol Glycidyl Ether.

Examination Requested: Approximate acute oral toxicity (LD_{50}) in rats.

Procedure: The acute (single dose) oral toxicity was determined in rats employing a modified procedure in "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, Published by the Association of Food and Drug Officials of the U.S. (1959)".

Animals: Adult albino rats BLU: (SD) BR Sprague-Dawley derived, were fasted for 18 hours prior to dosage with food and water ad libitum, after dosage. Groups of 5 males and 5 females were then intubated with the respective doses of the test material. Animals were observed daily for 14 days following administration of the test material, and deaths were recorded.

The acute oral toxicity LD_{50} for rats was calculated according to the method of Miller and Tainter (Proc. Soc. Biol. Med. 57, 261 (1944)).

Results and Summary: See Tables 1, 2, 3 and 4.

Conclusion: The approximate acute oral LD_{50} obtained for the test material identified above is 2.50 ± 0.11 ml per kg of body weight estimated by interpolation from the probit response curve.

Jean T. Griffiths
Jean T. Griffiths,
Study Director

John G. Babish, Ph.D.,
Staff Toxicologist,
Waverly Research Center

FDRL

Table 1

Preliminary Search

Dosage* Level ml/kg	No. Rats Dosed	Deaths Day 0	1	2	3	4	5	6	7	Mortality After 7 Days
1.0	2	0	0	0	0	0	0	0	0	0/2
2.5	2	1	1	-	-	-	-	-	-	2/2
5.0	2	1	1	-	-	-	-	-	-	2/2
10.0	2	1	1	-	-	-	-	-	-	2/2
15.0	2	2	-	-	-	-	-	-	-	2/2

* Administered as received.

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Table 2

Summary of LD_{50} Assay

Dosage Level ml/kg	No. Rats Dosed	Deaths Day 0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Mortality After 14 Days
.50*	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/10
1.50*	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/10
1.75*	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/10
2.00*	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/10
2.30**	10	2	4	0	0	1	1	0	0	0	0	0	0	0	0	0	8/10
2.50**	10	0	3	0	0	0	1	1	0	0	0	0	0	0	0	0	5/10
2.75**	10	0	8	2	-	-	-	-	-	-	-	-	-	-	-	-	10/10
3.25**	10	3	4	1	0	1	0	0	0	0	0	0	0	0	0	0	9/10
5.00*	10	4	3	0	2	1	-	-	-	-	-	-	-	-	-	-	10/10

* Administered as a 25% (v/v) corn oil solution.
** Administered as received.

FDRL

Table 3

Summary of Observations

Dose Level ml/kg	Symptoms	Necropsy Findings
.50*	Decreased activity.	No deaths.
1.50*	Decreased activity, Ataxia.	No deaths.
1.75*	Decreased activity, Ataxia.	No deaths.
2.00*	Decreased activity, Ataxia, Salivation, Urinary incontinence.	No deaths.
2.30**	Decreased activity, Ataxia, Salivation, Urinary incontinence, Tremors.	Lungs: dark. Liver: dark. Spleen: dark. Kidneys: pale. Intestines: contain a bloody substance.
2.50**	Decreased activity, Ataxia, Salivation, Urinary incontinence, Bloody nasal discharge, Rales.	Lungs: dark. Liver: dark. Spleen: dark and granular. Kidneys: dark and mottled. Intestines: contain a bloody substance.

* Administered as a 25% (v/v) corn oil solution.
** Administered as received.

(Continued)

FDRL

Table 3

Summary of Observations

Dose Level ml/kg	Symptoms	Necropsy Findings
Continued.		
2.75**	Decreased activity, Ataxia, Decreased respiration.	Lungs: dark and mottled. Liver: dark. Spleen: dark. Kidneys: dark. Intestines: contain a bloody substance.
3.25**	Decreased activity, Ataxia, Urinary incontinence, Bloody nasal discharge, Decreased respiration.	Lungs: dark and mottled. Liver: dark and granular. Spleen: dark and granular. Kidneys: dark. Intestines: contain a bloody substance.
5.00*	Decreased activity, Severe ataxia, Urinary incontinence.	Lungs: mottled. Liver: dark and mottled. Spleen: granular. Kidneys: dark and mottled. GI Tract: red in color. Skin: vascularized.

* Administered as a 25% (v/v) corn oil solution.
** Administered as received.

FDRL

Table 4

Individual Body Weight Data

(Males)

Dose Level ml/kg	Animal No. & Sex	Body Weights (g) Initial	Body Weights (g) 14 Days
.50*	6 M	275	320
	7 M	277	335
	8 M	280	353
	9 M	290	352
	10 M	177	251
	Average	260	322
1.50*	16 M	166	252
	17 M	190	308
	18 M	297	362
	19 M	280	272
	20 M	185	234
	Average	224	286
1.75*	26 M	172	267
	27 M	283	320
	28 M	260	319
	29 M	274	324
	30 M	180	286
	Average	234	303
2.00*	36 M	270	326
	37 M	273	319
	38 M	285	337
	39 M	185	277
	40 M	180	257
	Average	239	303

* Administered as a 25% (v/v) corn oil solution.

(Continued)

FDRL

Table 4

Individual Body Weight Data

(Males)

Dose Level ml/kg	Animal No. & Sex	Body Weights (g) Initial	Body Weights (g) 14 Days
Continued.			
2.30**	1 M	205	---
	2 M	247	298
	3 M	242	---
	4 M	240	---
	5 M	272	---
	Average	241	298
2.50**	11 M	225	240
	12 M	225	250
	13 M	235	---
	14 M	265	---
	15 M	253	---
	Average	241	245
2.75**	1 M	223	223
	2 M	228	---
	3 M	218	---
	4 M	201	---
	5 M	211	---
	Average	216	223
3.25**	11 M	190	---
	12 M	215	---
	13 M	216	---
	14 M	210	---
	15 M	205	---
	Average	207	-0-

** Administered as received.

(Continued)

FDRL

Table 4

Individual Body Weight Data

(Males)

Dose Level ml/kg	Animal No. & Sex	Body Weights (g) Initial	14 Days
Continued.			
5.00*	46 M	273	---
	47 M	290	---
	48 M	300	---
	49 M	180	---
	50 M	295	---
	Average	268	-0-

* Administered as a 25% (v/v) corn oil solution.

FDRL

Table 4

Individual Body Weight Data

(Females)

Dose Level ml/kg	Animal No. & Sex	Body Weights (g) Initial	Body Weights (g) 14 Days
.50*	11 F	160	193
	12 F	170	217
	13 F	210	257
	14 F	173	225
	15 F	162	194
	Average	175	217
1.50*	21 F	211	252
	22 F	165	222
	23 F	197	227
	24 F	195	243
	25 F	156	196
	Average	185	228
1.75*	31 F	250	239
	32 F	221	255
	33 F	195	225
	34 F	155	193
	35 F	215	265
	Average	207	235
2.00*	41 F	160	188
	42 F	175	197
	43 F	176	207
	44 F	175	184
	45 F	217	237
	Average	181	203

* Administered as a 25% (v/v) corn oil solution.

(Continued)

FDRL

Table 4

Individual Body Weight Data

(Females)

Dose Level ml/kg	Animal No. & Sex		Body Weights (g) Initial	14 Days
Continued.				
2.30**	6 F		120	---
	7 F		175	---
	8 F		177	210
	9 F		175	---
	10 F		180	---
		Average	165	210
2.50**	16 F		177	202
	17 F		182	---
	18 F		173	215
	19 F		183	215
	20 F		177	---
		Average	178	211
2.75**	6 F		177	---
	7 F		185	---
	8 F		175	---
	9 F		177	---
	10 F		195	---
		Average	182	-0-
3.25**	16 F		188	---
	17 F		173	---
	18 F		170	---
	19 F		165	185
	20 F		180	---
		Average	175	185

** Administered as received.

(Continued)

FDRL

Table 4

Individual Body Weight Data

Dose Level ml/kg	Animal No. & Sex	Body Weights (g) Initial	Body Weights (g) 14 Days
Continued.			
5.00*	51 F	165	---
	52 F	150	---
	53 F	145	---
	54 F	153	---
	55 F	160	---
	Average	155	-0-

* Administered as a 25% (v/v) corn oil solution.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
Rhône-Poulenc Inc.
CN 7500
Cranbury, New Jersey 08512-7500

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure 12075A

Triage of 8(e) Submissions

Date sent to triage: AUG 2 4 1985

NON-CAP (CAP)

Submission number: 12075A

TSCA Inventory: (Y) N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

(ATOX) SBTOX SEN (w/NEUR)

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: (0) 1 2 **pages** 1,2 **pages** 1-3

Notes:

Contractor reviewer : UDS **Date:** 3/10/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1192 -12075 SEQ. A

TYPE: (INT) SUPP FLWP

SUBMITTER NAME: Rhone-Poulenc Inc.

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
(0678) CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 10/27/92 OTS DATE: 11/02/92 CSRAD DATE: 02/07/95

CHEMICAL NAME:
Glycol Glycidyl Ether
DV 1143

CAS#
2224-15-9
11

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
(0209)	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
(0243)	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:

NON-CBI INVENTORY
(YES)
NO
IN TERMINI

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REFER

SPECIES
RAT

TOXICOLOGICAL CONCERN:
(LOW)
MED
HIGH

USE:

PRODUCTION:

CAS SR

COMMENTS

-CPSS-

> <ID NUMBER>
8(E)-12075A

> <TOX CONCERN>
L/L

> <COMMENT>
ACUTE ORAL TOXICITY IN ADULT MALE AND FEMALE SPRAGUE-DAWLEY RATS IS OF LOW CONCERN. SINGLE ORAL DOSES OF 1.0, 2.5, 5.0, 10.0 AND 15.00 ML/KG GAVAGED TO 2 RATS EACH WERE ASSOCIATED WITH DEATH OF ALL BUT THE TWO ANIMALS OF A 1.0 ML/KG DOSAGE. THIS RANGE-FINDING STUDY DID NOT REPORT ANY SIGNS OF TOXICITY OBSERVED.

.
ACUTE ORAL TOXICITY IN ADULT MALE AND FEMALE SPRAGUE-DAWLEY RATS IS OF LOW CONCERN. SINGLE ORAL DOSES OF 0.5, 1.5, 1.75, 2.00, 2.30, 2.50, 2.75, 3.25 AND 5 ML/KG GAVAGED TO GROUPS OF 10 EACH ADULT RATS (1:1 MALE, FEMALE) WERE ASSOCIATED WITH SIGNS OF NEUROTOXICITY AND MORTALITY AS FOLLOWS: 0.50 - 2.00 ML/KG (0/40), 2.30 ML/KG (8/10), 2.50 ML/KG (5/10), 2.75 ML/KG (10/10), 3.25 ML/KG (9/10), 5.00 ML/KG (10/10). AN ORAL LD50 WAS 2.50 +/- 0.11 ML. SIGNS OF TOXICITY WERE DOSE DEPENDENT AND INCLUDED DECREASED ACTIVITY, ATAXIA, SALIVATION, URINARY INCONTINENCE, TREMORS, BLOODY NASAL DISCHARGE, RALES, DECREASED RESPIRATION AND DEATH. POSTMORTEM NECROPSY REVEALED DARK DISCOLORATION OF LUNGS, LIVER AND SPLEEN, PALE KIDNEYS, INTESTINES CONTAINING BLOODY SUBSTANCE, RED GI TRACT AND VASCULARIZED SKIN. ANIMALS SURVIVING LETHAL DOSES TO THE END OF 14-DAY OBSERVATION ALSO EXHIBITED REDUCED WEIGHT GAIN.

$$$$